MINISTÈRE
DE L'ENSEIGNEMENT
SUPÉRIEUR,
DE LA RECHERCHE
ET DE L'INNOVATION

Liberté
Égalité
Fraternité

horizon europe

Webinar 2: Concrete example of an ethics section of a project for submission

horizon-europe.gouv.fr

Vania Rosas, NCP Health, MESRI, vania.rosas-magallanes@recherche.gouv.fr

Webinaires éthique pour la CE

Webinaire 1 : La section éthique dans les dossiers de soumission- disponible ici:

https://www.horizon-europe.gouv.fr/webinaire-ethique-dans-les-projets-europeens-13-29140

Webinaire 2 : Exemple concret de section éthique dans une soumission de projet européen- Mardi 25 janvier 2022, 11h00 - 12h00

Webinaire 3 : Echange de bonnes pratiques - réglementation et adhésion des chercheurs- Mardi 1 février 2022, 14h00 - 15h00

- Human Embryonic stem cells and human embryos
- Human participants to the research
- Personal data
- Artificial intelligence
- Potential misuse of results
- Other ethics issues (animals, etc.)
- Comment motiver les chercheurs à bien répondre à la section éthique d'un projet Européen

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

Webinar content

- Ethics issues checklist
- Ethics issues table
- The questions in the ethics issues table
- How to answer to the ehics issues section: example
- Annex or not annex?

It is important to reflect upon ethical issues when planning a research project. Taking the time to consider all the potential risks, It will also improve the quality of your research plan and facilitate its implementation

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

Ethics checklist Horizon Europe

- Applicant declarations part A – All proposals stage 1 and stage 2
- Ethics Issues table questions in part A - only stage 2 ou single stage
- Ethics self-assessment + annex if needed/possible - only stage 2 ou single stage
- If you have identified serious/complex issues: risk-management measures - only stage 2 ou single stage

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

Who is responsible?

Coordinator:

- Gathers all the information of the consortium
- Main contact with the EC if the project is funded
- Answers to the EC questions on ethics before and after the GA is signed
- Keeps on file the relevant authorisations
- Responsible for its own research

Partner:

- Answers correctly to the coordinator all the requests at any phase of the project
- The coordinator cannot substitute to the partner on the ethics issues
- Keeps on file the relevant authorisations

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

Where do you can find help to answer ?

1. **Your first source should always be at your institution**
   - specialised ethics and compliance departments
   - relevant compliance managers
   - ethics committees
   - ethics advisors in your institution
   - data protection officers

2. **How to complete your ethics self-assessment**

3. **For projects with a significant ethics dimension, consider involving/appointing an ethics advisor/advisory board.**

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

1) Applicant declarations related to ethics

Research Integrity

6) We declare that the proposal complies with ethical principles (including the highest standards of research integrity as set out in the ALLEA European Code of Conduct for Research Integrity, as well as applicable international and national law, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. Appropriate procedures, policies and structures are in place to foster responsible research practices, to prevent questionable research practices and research misconduct, and to handle allegations of breaches of the principles and standards in the Code of Conduct.

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

Applicant declarations related to ethics

Civil applications and activities excluded from funding

7) We declare that the proposal has an exclusive focus on civil applications (activities intended to be used in military application or aiming to serve military purposes cannot be funded). If the project involves dual-use items in the sense of Regulation 428/2009, or other items for which authorisation is required, we confirm that we will comply with the applicable regulatory framework (e.g. obtain export/import licences before these items are used).	☐
8) We confirm that the activities proposed do not – aim at human cloning for reproductive purposes; – intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or – intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer. – lead to the destruction of human embryos (for example, for obtaining stem cells) These activities are excluded from funding.	☐

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

2) Ethics issues table questions

1. Human Embryonic Stem Cells (hESC) and Human Embryos (hE)
2. Human participants
3. Human cells/tissues
4. Personal data
5. Animals
6. Non-EU Countries
7. Environment & Health and Safety
8. Artificial Intelligence
9. Other ethics issues
10. Cross-cutting issue: potential misuse of results

- ***Needs to be completed in part A***
- ***If you say YES to one or more of the questions, you need to explain further (with an ethics annex if needed)***

2) Ethics self assessment
Question 1: on stem cells and embryos

4 - Ethics & security

Ethics Issues Table ?

1. Human Embryonic Stem Cells and Human Embryos			Page
Does this activity involve Human Embryonic Stem Cells (hESCs)?	◉ Yes	○ No	
Will they be directly derived from embryos within this project?	○ Yes	◉ No	
Are they previously established cells lines?	○ Yes	◉ No	
Are the cell lines registered in the European registry for human embryonic stem cell lines	○ Yes	◉ No	
Does this activity involve the use of human embryos?	◉ Yes	○ No	
Will the activity lead to their destruction?	○ Yes	◉ No	

- *No funding for human cloning for reproductive purposes*
- *No funding for modifying the genetic heritage of human beings, heritable;*
- *No funding for the creating human embryos for research or stem cell procurement, including by means of somatic cell nuclear transfer.*

Human Embryos	human Embryonic stem cells (hESC)
Why do you need to use embryos, describe in detail, where are they coming from? Do you have the consent forms from the parents?	Describe the origin and cell lines and use of the cell lines in your research. Are they already in the European registry

Serious/complex issue!!!

In France: https://www.agence-biomedecine.fr/Recherches-sur-l-embryon-humain-et-les-cellules-souches-embryonnaires-humaines

Elsewhere ask your partners!!

MINISTÈRE
DE L'ENSEIGNEMENT
SUPÉRIEUR,
DE LA RECHERCHE
ET DE L'INNOVATION

Regulation is different in each country

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

Question 2: Human participants

2. Humans	
Does this activity involve human participants?	◉ Yes ○ No
Are they volunteers for non medical studies (e.g. social or human sciences research)?	○ Yes ◉ No
Are they healthy volunteers for medical studies?	○ Yes ◉ No
Are they patients for medical studies?	○ Yes ◉ No
Are they potentially vulnerable individuals or groups?	○ Yes ◉ No
Are they children/minors?	○ Yes ◉ No
Are they other persons unable to give informed consent?	○ Yes ◉ No
Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants?	◉ Yes ○ No
Does it involve invasive techniques?	○ Yes ◉ No
Does it involve collection of biological samples?	○ Yes ◉ No
Does this activity involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)	◉ Yes ○ No
Is it a clinical trial?	○ Yes ◉ No
Is it a low-intervention clinical trial?	○ Yes ◉ No

For Horizon Europe: collection of biological samples, personal data, medical interventions, interviews, observations, tracking or the secondary use of information provided for other purposes, e.g. other projects, officially collected information, social media sites, etc

The main ethics issues concern:

- *the respect for persons and for human dignity*
- *fair distribution of benefits and burden*
- *the rights and interests of the participants*
- *the need to ensure participants' free informed consent (with particular attention to vulnerable categories of individuals such as children, patients, discriminated people, minorities, persons unable to give consent, etc.).*

Detail the protocols (criteria and IC procedures, vulnerable populations, incidental findings, mitigation risks, etc.). Can include a clinical studies form, depending on the call.

In France: Depending on the research: Comité de Protection de Personnes and/or Institutional Review Board

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

Question 3: Human cells/tissues

3. Human Cells / Tissues (not covered by section 1)		Page
Does this activity involve the use of human cells or tissues?	◉ Yes ○ No	
Are they human embryonic or foetal cells or tissues?	○ Yes ◉ No	
Are they available commercially?	○ Yes ◉ No	
Are they obtained within this project?	○ Yes ◉ No	
Are they obtained from another project, laboratory or institution?	○ Yes ◉ No	
Are they obtained from biobank?	○ Yes ◉ No	

-Describe why are you using human cells and how

In France: It depends on your answer (if your are collecting them, refer to Question 2, if you are buying them and your will stock them, if you are going import/export, are they in a biobank). CSP that rules on the donation of cells and tissues

Declaration from the Institution to MESRI (or not), MTAs? Etc.

This section refers to projects with activities using, producing or collecting human cells and tissues

The main obligations are to:

- *keep track of the origin of the cells and tissues you use, produce or collect*

and to obtain:

- *the necessary accreditation/designation/authorisation/licensing for using, producing or collecting the cells or tissues*
- *free and fully informed consent of the donors.*

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

Question 4: Personal data

4. Personal Data		
Does this activity involve processing of personal data?	◉ Yes	○ No
Does it involve the processing of special categories of personal data (e.g.: genetic, biometric and health data, sexual lifestyle, ethnicity, political opinion, religious or philosophical beliefs)?	◉ Yes	○ No
Does it involve processing of genetic, biometric or health data?	○ Yes	◉ No
Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (such as, surveillance, geolocation tracking etc.)?	◉ Yes	○ No
Does this activity involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)?	◉ Yes	○ No
Is it planned to export personal data from the EU to non-EU countries? Specify the type of personal data and countries involved	○ Yes	◉ No
Is it planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country? Specify the type of personal data and countries involved	○ Yes	◉ No
Does this activity involve the processing of personal data related to criminal convictions or offences?	◉ Yes	○ No

Describe the data you are collecting, depending on your answer refer to question 2. Anonymised or pseudo anonymised your data? Describe if you need to collect/share it, etc. describe the methods. Sensitive data? Do other countries collaborating with you are submitted to the GDPR, how you will handle it?

In France: We are submitted to the GDPR. Involve your DPO on the process if possible.

This section concerns projects with research activities that involve processing of personal data, regardless of the method used (e.g. interviews, surveys, questionnaires, direct online retrieval etc.).

Personal data — Information relating to an identified or identifiable natural person. Also Processing personal data

Examples: name, address, identification number, occupation, e-mail, CV, location data, phone number, data provided by smart meters, data held by a hospital or doctor.

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

Question 5: Animals

5. Animals		
Does this activity involve animals?	◉ Yes	○ No
Are they vertebrates?	○ Yes	◉ No
Are they non-human primates? (NHP)	○ Yes	◉ No
Are they genetically modified?	○ Yes	◉ No
Are they cloned farm animals?	○ Yes	◉ No
Are they endangered species?	○ Yes	◉ No

Describe the protocols, the number of animals, why do you need to use animals for your research instead of an alternative.

In France: Protocols are submitted to CETEAs that submit them to the French Agricultural Ministry. GMO authorisations as well (question 7). Animal handling training from the users (institutions).

This section refers to the projects with research activities involving animals

Animal welfare

You must choose alternatives to animal use where possible and implement the principles of replacement, reduction and refinement ('three Rs').

Non-human primates (NHPs) — Since non-human primates are so close to human beings. Their use in experiments raises particular ethics concerns, as well as endangered species.

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

Question 6: Non-EU Countries

6. Non-EU Countries			Page
Will some of the activities be carried out in non-EU countries?	○ Yes	◉ No	
In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues?	○ Yes	◉ No	
It is planned to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?	○ Yes	◉ No	
Is it planned to import any material (other than data) from non-EU countries into the EU or from a non-EU country to another non-EU country? For data imports, see section 4.	○ Yes	◉ No	
Is it planned to export any material (other than data) from the EU to non-EU countries? For data exports, see section 4.	○ Yes	◉ No	
Does this activity involve low and/or lower middle income countries, (if yes, detail the benefit-sharing actions planned in the self-assessment)	◉ Yes	○ No	
Could the situation in the country put the individuals taking part in the activity at risk?	◉ Yes	○ No	

This section concerns projects with activities involving non-EU countries.
This is the case where:

- *activities are conducted, partially or wholly, in a non-EU country*
- *participants or resources come from a non-EU country*
- *material is imported from or exported to a non-EU country.*

Ethical issues (particularly in developing countries), such as:

- *exploitation of participants*
- *exploitation of local resources*
- *risks to project teams and staff*
- *activities (especially research) that are prohibited in the EU.*

For Horizon Europe, the activities must ALSO be allowed in at least one Member State. Describe how are you going to interact with this countries, maybe you have already describe it in other sections

In France: MTAs? Nagoya protocol on Acces and Benefit Sharing for genetic resources

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

Question 7: Environment, health and safety

7. Environment, Health and Safety			Page
Does this activity involve the use of substances or processes that may cause harm to the environment, to animals or plants.(during the implementation of the activity or further to the use of the results, as a possible impact) ?	◉ Yes	○ No	
Does this activity deal with endangered fauna and/or flora / protected areas?	◉ Yes	○ No	
Does this activity involve the use of substances or processes that may cause harm to humans, including those performing the activity.(during the implementation of the activity or further to the use of the results, as a possible impact) ?	◉ Yes	○ No	

Health and safety, laboratories classification, specific safety practices, mitigation or risks, biological and chemical waste handling, radioactivity, work in the field? Describe all that is needed

In France: GMO authorisations, safety classifications of the laboratoires, host institution safety procedures

This section concerns projects with activities that may adversely affect:

- *the environment or*
- *the health and safety of the persons involved.*

This may be due to any of the following:

- *the (experimental) design of the project itself (— especially for research projects)*
- *undesirable side-effects of the technologies used.*

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

Question 8: Artificial intelligence (New)

8. Artificial Intelligence

Does this activity involve the development, deployment and/or use of Artificial Intelligence? (if yes, detail in the self-assessment whether that could raise ethical concerns related to human rights and values and detail how this will be addressed). ◉ Yes ○ No

Describe the manner in which an AI solution is deployed or used may change the ethical characteristics of the system.

The involvement of an ethics advisor/ethics advisory board with appropriate expertise in ethics of new and emerging technologies is highly recommended for projects which may raise significant ethics risks. This is particularly relevant for systems that have the potential to lead to significant negative individual, social and environmental impacts; stigmatisation or discrimination of people; interaction, replacement or influence on human decision-making processes.

This section concerns projects with activities involving the development, deployment and/or use of artificial intelligence (AI)-based systems or techniques.

This requires specific ethically-focused approach during the development, deployment, and/or use of AI-based solutions.

Any use of AI systems or techniques should be clearly described in the project and you must demonstrate their technical robustness and safety (they must be dependable and resilient to changes).

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

Artificial Intelligence

Does the proposed activity involve the development, deployment and/or use of Artificial Intelligence?

- Could AI system/technique **stigmatise or discriminate** against people (based on sex, race, ethnic social origin, age, disability, sexual orientation, religion, political affiliation, etc.)?

- Does the AI system/**technique interact, replace or influence human decision-making processes** (e.g. issues affecting human life, health, well-being or human rights, or economic, social or political decisions)?

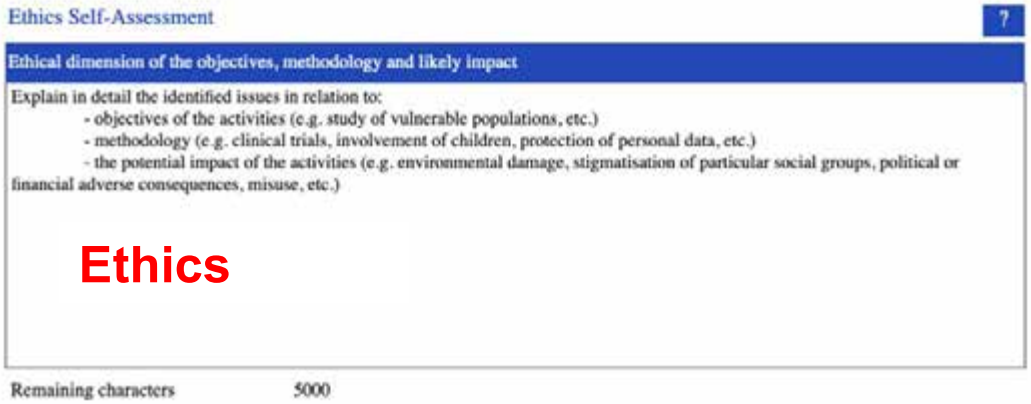
MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

2) Ethics issues table questions

1. Human Embryonic Stem Cells (hESC) and Human Embryos (hE)
2. Human participants
3. Human cells/tissues
4. Personal data
5. Animals
6. Non-EU Countries
7. Environment & Health and Safety
8. Artificial Intelligence
9. Other ethics issues
10. Cross-cutting issue: potential misuse of results

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

Self-assessment proposal application form


Ethics Self-Assessment ?

Ethical dimension of the objectives, methodology and likely impact

Explain in detail the identified issues in relation to:
- objectives of the activities (e.g. study of vulnerable populations, etc.)
- methodology (e.g. clinical trials, involvement of children, protection of personal data, etc.)
- the potential impact of the activities (e.g. environmental damage, stigmatisation of particular social groups, political or financial adverse consequences, misuse, etc.)

Ethics

Remaining characters 5000

For example, you can answer the following:

We have identified in this project the following ethics issues: :

- *Research involving human participants;*
- *Research involving human cells and tissues;*
- *Research involving personal data;*
- *Research involving animals;*
- *Research involving non-EU countries, including low and/or lower-middle income*
- *countries;*
- *Research involving the use of elements that may cause harm to humans and to the*
- *environment.*

Describe briefly every aspect, one phrase and raise potential ethics issues. *We are aware of… we will describe further in an annex….*

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

Self-assessment proposal application form

Compliance with ethical principles and relevant legislations
Describe how the issue(s) identified in the ethics issues table above will be addressed in order to adhere to the ethical principles and what will be done to ensure that the activities are compliant with the EU/national legal and ethical requirements of the country or countries where the tasks are to be carried out. It is reminded that for activities performed in a non-EU countries, they should also be allowed in at least one EU Member State.

Regulation

We will comply with:

We engage to have the relevant authorisations before the starting of the research with human participants according to
We will comply with Directive xxxx or we have complied with Directive xxxx, but DO NOT make a copy-paste of a phrase of an old project.
Please ask the researchers of not doing that, no problem if you do not know what is the law or the directive, etc. engage to comply.

Project from CORDIS

Public summary from: https://cordis.europa.eu/result/rcn/202790_en.html

Project: Novel cells sourced for liver therapy . This is a project that has 3 European partners: one in France, one in Spain and one in Belgium.

New cell-based therapies constitute promising alternatives for the treatment of inborn metabolic disorders. European scientists discovered an expandable **cell source** for liver therapy that could also be used for drug screening purposes. The Crigler-Najjar disease is a rare metabolic disorder of the liver associated with an inability to metabolise bilirubin, the by-product of haem breakdown in red blood cells. Patients present with jaundice and the only cure is liver transplantation, which however, is limited by the shortage of donors.

Transplantation of **genetically corrected hepatocytes** has been proposed as an attractive alternative but it is hampered by the low amplification potential of these cells in vitro. Standard methods of iPSC generation induce genetic and epigenetic anomalies, which decrease the efficiency of reprogramming and re-differentiation, and may lead to long-term complications. Scientists of the EU-funded CN-I LIVER THERAPY (Potential of induced pluripotent stem cells for the treatment of Crigler-Najjar liver disease**: a preclinical safety assessment**) project proposed to derive **liver cells from induced pluripotent stem cells (iPSC**). They developed a novel method for inducing proliferative hepatic progenitor cells (iHPC) **from human hepatocytes** to overcome previously encountered issues. These iHPCs were obtained by culturing **primary hepatocytes in** dedifferentiating medium containing a cocktail of growth factors and small molecules for seven days. Transcriptome analysis revealed interesting similarities between hepatocyte reprogramming to pluripotency and dedifferentiation. However, iHPCs exhibited fewer mutations compared to iPSC generated-hepatocytes.

To address the safety of **iHPC transplantation, scientists injected cells into the liver of immuno-deficient mice**. Results showed efficient iHPC differentiation in vivo without triggering detectable tumour development. The CN-I LIVER THERAPY team have applied for a European patent to protect the intellectual property of the method. Apart from cell therapy, these iHPC cells could be used for personalised drug testing in existing rodent animal models and in vitro assays used by pharmaceutical companies**. iHPCs can be readily generated and expanded from a small number of patient cells**. As such, they constitute an ideal cell source for predicting drug metabolic stability and clearance as well as liver toxicity. Furthermore, the plasticity of human hepatocytes provides a promising methodological lead for the development of a bio-artificial liver.

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

2) Ethics issues table questions

1. Human Embryonic Stem Cells (hESC) and Human Embryos (hE)
2. Human participants
3. Human cells/tissues
4. Personal data
5. Animals
6. Non-EU Countries
7. Environment & Health and Safety
8. Artificial Intelligence
9. Other ethics issues
10. Cross-cutting issue: potential misuse of results

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

2) Ethics issues table questions in this example

2. Humans		Page
Does this activity involve human participants?	◉ Yes ○ No	
Are they volunteers for non medical studies (e.g. social or human sciences research)?	○ Yes ◉ No	
Are they healthy volunteers for medical studies?	○ Yes ◉ No	
Are they patients for medical studies?	◉ Yes ○ No	
Are they potentially vulnerable individuals or groups?	○ Yes ◉ No	
Are they children/minors?	○ Yes ◉ No	
Are they other persons unable to give informed consent?	○ Yes ◉ No	
Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants?	◉ Yes ○ No	
Does it involve invasive techniques?	◉ Yes ○ No	
Does it involve collection of biological samples?	◉ Yes ○ No	
Does this activity involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)	○ Yes ◉ No	

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

In this example

3. Human Cells / Tissues (not covered by section 1)		Page
Does this activity involve the use of human cells or tissues?	(●) Yes ( ) No	
Are they human embryonic or foetal cells or tissues?	( ) Yes (●) No	
Are they available commercially?	( ) Yes (●) No	
Are they obtained within this project?	(●) Yes ( ) No	
Are they obtained from another project, laboratory or institution?	( ) Yes (●) No	
Are they obtained from biobank?	( ) Yes (●) No	

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

In this example

4. Personal Data		Page
Does this activity involve processing of personal data?	(●) Yes ( ) No	
Does it involve the processing of special categories of personal data (e.g.: genetic, biometric and health data, sexual lifestyle, ethnicity, political opinion, religious or philosophical beliefs)?	( ) Yes (●) No	
Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (such as, surveillance, geolocation tracking etc.)?	( ) Yes (●) No	
Does this activity involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)?	( ) Yes (●) No	
Is it planned to export personal data from the EU to non-EU countries? Specify the type of personal data and countries involved	( ) Yes (●) No	
Is it planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country? Specify the type of personal data and countries involved	( ) Yes (●) No	
Does this activity involve the processing of personal data related to criminal convictions or offences?	( ) Yes (●) No	

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

In this example

5. Animals		Page
Does this activity involve animals?	◉ Yes ○ No	
Are they vertebrates?	◉ Yes ○ No	
Are they non-human primates? (NHP)	○ Yes ◉ No	
Are they genetically modified?	◉ Yes ○ No	
Are they cloned farm animals?	○ Yes ◉ No	
Are they endangered species?	○ Yes ◉ No	

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

In this example

7. Environment, Health and Safety			Page
Does this activity involve the use of substances or processes that may cause harm to the environment, to animals or plants.(during the implementation of the activity or further to the use of the results, as a possible impact) ?	(●) Yes	( ) No	
Does this activity deal with endangered fauna and/or flora / protected areas?	( ) Yes	(●) No	
Does this activity involve the use of substances or processes that may cause harm to humans, including those performing the activity.(during the implementation of the activity or further to the use of the results, as a possible impact) ?	(●) Yes	( ) No	

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

In this example

Ethics Self-Assessment

?

Ethical dimension of the objectives, methodology and likely impact

We have identified in this project the following ethics issues:
Research involving human participants (Spain)*: we will collect samples from Crigler-Najjar patients human hepatocytes during xxx intervention, etc. and this will be further described on the ethics annex and clinical trial template that includes the protocol for collecting cells*
Research involving human cells and tissues (France and Belgium)*: Our partners in France and Belgium will be in charge of dedifferentiate human hepatocytes from Crigler-Najjar patients to hiPSC to modify and differentiate to corrected hepatocytes that will be transplanted into mice and further description on the protocols will be included on the ethisc annex*
Research involving personal data (All partners)*: The only information that was collected was if the patien was a carrier of the Crigler-Najjar syndrome. The rest of the information was pseudo anonymised etc.*
Research involving animals France) *: For preclinical research we have used XXXs immunocompromised humanised mice carrying xxxsss genotype that were created through the xxxsss platform with this and this characteristics relevant to the research;*
Research involving the use of elements that may cause harm to humans and to the Environment *: in our institutions, this and this measures were implemented for chemical and biological waste. For the modification of xxxsss animals we work on P2 laboratories…;*

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

In this example

Completely fictional, you need to adapt it to the reality

Compliance with ethical principles and relevant legislations

For this research we have obtained the authorisation of the relevant authorities in Spain partner participating at human research. The relevant authorisation is provided in annex I regarding the protocol to collect the Crigler-Najjar patient cells during the lifetime of the project called xxxx.

For the human cells and tissues that will be dedifferentiated and then differentiated into corrected hepatocytes in France and Belgium, we engage to comply with the CSPXXX (France) that rules on the collection and stock of human cells in the laboratories

The only personal data that will be stored at the project databases is that concerning the carrying of the Crigler-Najjar syndrome. The rest of the information was pseudoanonymised through this and this method.

Etc. etc.

This is a method, a possibility, not only a way of doing it, there are many ways!! The importance is to be aware of what you need to know at the moment of the research in terms of ethics and regulation

Annex or not Annex?

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

Annex or not annex?

Yes, if possible! Because

1) Human participants
2) Human cells and tissues (induced pluripotent stem cells)
3) Animals
4) Data
5) Environment health and safety

Do we need to appoint an ethics advisor or board?

I would at least recommend an ethics advisor and I will budget her/his participation to the project

1. How to complete your ethics self-assessment

2. Your first source should always be at your institution

3. For projects with a significant ethics dimension, consider involving/appointing an ethics advisor/advisory board

4. The better you answer, the easiest will be during the GA signature and follow-up of the the project

5. Ethics by design?